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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------|----------------------|--------------------------|------------------|
| 10/671,144 | 09/24/2003 | Yossi Gross | NY-COLB 202.1-Cont-US | 4554 |
| 24972 | 7590 | 07/18/2007 | EXAMINER | |
| FULBRIGHT & JAWORSKI, LLP | | | LACYK, JOHN P | |
| 666 FIFTH AVE | | | ART UNIT | PAPER NUMBER |
| NEW YORK, NY 10103-3198 | | | 3735 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 07/18/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/671,144

Applicant(s)

GROSS ET AL.

Examiner

John P. Lacyk

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 243-274 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 243-274 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/10/03;
8/20/04; 12/15/04; 5/06/05; 11/29/06.

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent, and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 243-274 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-13, 17-20, 22-25 of U.S. Patent No. 6,896,651. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are directed to methods for treating incontinence by implanting an electrode in a pelvic muscle and applying or driving an electrical waveform to the muscle. The patented claims further include analyzing signals indicative of abdominal pressure or strain, however the elimination of an element and subsequent loss of its function is considered to have been obvious if the remaining elements perform the same functions as before. Also the pending claims include a range of waveform pulse width durations in which the device can clearly be set to any desired duration of pulse widths and would have been obvious based upon the intended use and particulars of each individual patient.

Art Unit: 3735

3. Claims 243-274 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-18, 21, 23-24, 46-51, 53 of U.S. Patent No. 6,652,449. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to methods for treating incontinence by implanting an electrode in the pelvic muscle and applying or driving an electrical waveform to the muscle. As discussed above the patented claims further include a step of analyzing signals to apply the waveform responsive to the analysis however the loss of this step is considered to have been an obvious expedient since the remaining elements perform the same function as before and to choose any desired range of pulse width durations would have further been an obvious expedient.

4. Claims 243-274 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40, 44, 46-50, 52, 61-62, 69 of U.S. Patent No. 6,354,991. Although the conflicting claims are not identical, they are not patentably distinct from each other for the same reasons as discussed above.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 243-274 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suda et al (5,978,712).

Art Unit: 3735

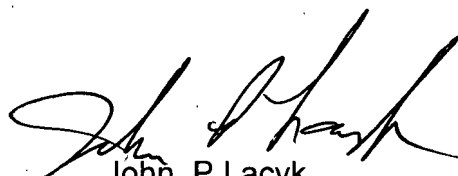
Suda et al discloses (column 1, lines 15-29) discloses that methods are well known in the art to treat incontinence by implanting electrodes that are "directly embedded into the pelvic floor muscles" to provide electrical stimulation to the muscles and that the intensity, frequency stimulation period and the like depend on cases and individual differences. Suda et al discloses the claimed methods except for specifically teaching a pulse width duration between 0.1 ms and 2 ms, although Suda et al does teach that many parameters may be varied depending on the individual and particular cases. Therefore a modification of Suda et al such that the electrical stimulation is delivered to the pelvic muscle to treat incontinence at the particular pulse width duration would have been obvious to one skilled in the art since it is considered to be a matter of routine engineering design choice to discover the optimum or workable ranges and the particular ranges must produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Richmond et al (6,061,596) is cited to further show implanting electrodes into the pelvic muscle for stimulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



John P Lacyk
Primary Examiner
Art Unit 3735

J.P. Lacyk